

CEDAC FINAL RECOMMENDATION and REASONS for RECOMMENDATION

PEGAPTANIB SODIUM (Macugen[™] – Pfizer Canada Inc.)

Description:

Pegaptanib is a selective vascular endothelial growth factor (VEGF) antagonist with anti-angiogenesis effects. It is approved for the treatment of subfoveal choroidal neovascularization (CNV) secondary to age-related macular degeneration (AMD).

Dosage Form:

0.3 mg/90 µL prefilled syringe for intravitreal injection

Recommendation:

The Canadian Expert Drug Advisory Committee (CEDAC) recommends that pegaptanib not be listed.

Reasons for the Recommendation:

1. The Committee recognizes the impact of AMD and vision loss in elderly Canadians and that there is a need for effective therapies for this condition. Pegaptanib is the only therapy approved by Health Canada for use in all forms of subfoveal wet AMD. The Committee considered the results of two identically designed double-masked, randomized controlled trials (RCTs) that compared three doses of pegaptanib (0.3, 1 or 3 mg) with a sham procedure, administered into one eye per patient every six weeks for one year. When compared to the sham treated group, pegaptanib, at the approved dosage of 0.3 mg, resulted in statistically significant improvements in the number of patients who experienced loss of less than 3 lines of visual acuity (70% of pegaptanib treated patients vs 55% of sham treated patients) and the number of patients who gained ≥ 3 lines of visual acuity (6% of pegaptanib treated patients vs 2% of sham treated patients).

The Committee considered patient drop-out rates in the pegaptanib groups during the second year of the RCTs (13% and 27%) to be too great to reliably assess the effectiveness of pegaptanib beyond one year of treatment.

2. The benefits of pegaptanib on visual acuity were assessed in the study eye only and effects on overall visual function using both eyes are not clear. In the one RCT that measured changes in quality of life, there was no significant difference between pegaptanib and sham treated patients.
3. Pegaptanib costs \$995 per dose or \$7960 per year. The economic model submitted by the manufacturer reported an incremental cost-effectiveness ratio of \$59,000 per quality-adjusted life year (QALY) when compared to standard care. This analysis was conducted over a lifetime time

horizon, though there is uncertainty whether the clinical benefit from pegaptanib persists beyond one year of treatment. Therefore the true cost effectiveness of pegaptanib will likely be significantly higher than this. As such, at the current price, the committee did not consider pegaptanib to be cost-effective.

Of Note:

1. Both published and unpublished information were reviewed and taken into consideration in making this recommendation.
2. Pegaptanib is administered by intravitreal injection and in the RCTs pegaptanib treated patients developed endophthalmitis (1.3% of patients), retinal detachment (0.7% of patients) and traumatic injury to the lens (0.6% of patients).